Design and Development of A New Biomedical Instrument

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ABSTRACT

A new biomedical instrument is introduced to apply multiple surgical clips to patients' tissue or vessel. In the surgical process, the instrument jaw is placed around the tissue or other organ structure. When bring the handles of instrument together, the clip can close and secure the tissue or vessel to prevent them from bleeding. With the release of handles, next surgical clip is automatically loaded into the instrument jaw. This latest design shows several potential features to help surgeons' operational procedure if compared with current surgical clip instrument, including advanced mechanism proposed to eliminate the accident shooting out when surgical clip is loaded into jaws, strong structure designed to reduce the jaws twist that can damage tissues, enhanced supporting feature added to prevent accident jaw closure when extra side-load exerted, and etc. The instrument is analyzed by computer modeling and simulation to prove its feasible performance with good mechanical advantage.

Keywords: surgical instrument, Mechanical advantage, minimal tissue invasion, surgiclip, trauma prevention

INTRODUCTION

The ligation of blood vessels, severed tissues and/or other organs to stop bleeding are required during surgical procedures. Surgical clip appliers to quickly apply the surgical clip onto organ, vessel or tissue are known for years. These surgical clip appliers include the applications of single and multiple clip procedures. In single clip surgical procedure, a new clip will be added to the instrument after applying each clip. In multiple clip surgical procedure, multiple clips can be sequentially applied to vessel and organ. The surgical clip instruments usually have a trigger/handle mechanism, a major unit body, a clip crimping system and several other functioning parts including a pair of jaws. This improved surgical clip instrument is proposed for the open/endoscopic surgical applications. Although currently a few of surgical clip instruments for continuous clip advance have been proposed, a further improvement for proper clip delivery instrument with less complicated mechanism and high reliability is required to have the effective occlusion of a blood vessel. Some issues arise often where the surgical clip device can be manipulated while not in operation, i.e. a surgical tray is being loaded prior to surgery. This unexpected motion can cause the trigger handle accidental movement causing the unwanted jaw compression. Other problems include that the surgical clip can be fired without the surgeons' aware of no remaining clips in the instrument which can sever or damage the tissues when close the device jaws. All these potential problems have been resolved by the improved mechanism design in this new biomedical/surgical clip

PRINCIPLE OF NEW SURGICAL CLIP INSTRUMENT

This new biomedical/surgical clip instrument is shown in Figs. 1 – 3. First the instrument is placed onto patient's body vessel/tissue and then clip is advanced to the jaws. The surgical clip will be applied and secured onto the vessel/tissue when trigger/handles are closed by surgeons. When trigger/handles are released, the instrument jaws are open and the clip pusher bar and trigger/handles can return to their original positions for unit next firing cycle. Compared with today's existing clip advancing mechanism in which the clip is advanced to the jaws by compression spring that sometime causes the clip's accidentally shooting from instrument, the clip advanced into the jaws in this improved instrument design is well guided and controlled. The clip pusher bar linked to the pivot pin on the trigger handles moves distally to advance the clip into jaws when instrument handles start to be closed by surgeons. This linear motion of the clip can be well controlled by surgeons in order to keep the clip from accidentally shooting out of the instrument. Another potential issue in the surgeon's procedure is that the jaws might be twist if extra external load presented while surgeon applies the device onto the thick tissue or vessel, bone frame and other strong organ areas. A supported structure is designed in this new instrument to keep the jaws from twist. In addition, a well-controlled movable wedge plate is inserted between the pair of jaws at the time the trigger handles are released to keep the instrument from being manipulated while not in operation. The prototype of this new design indicated the feasible and proper functionality.

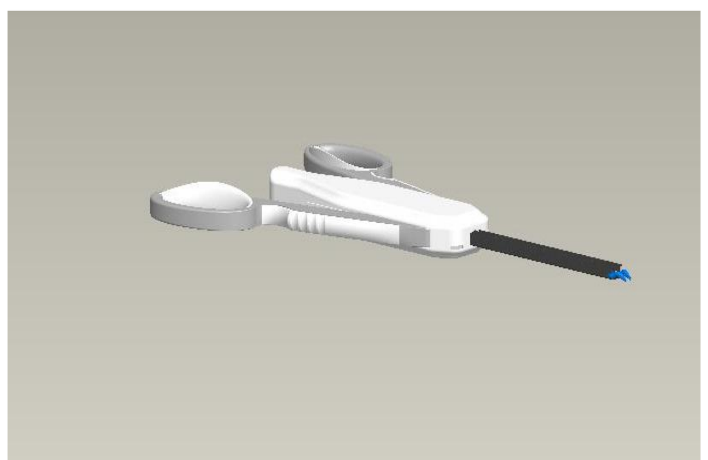

Fig. 1 Biomedical instrument

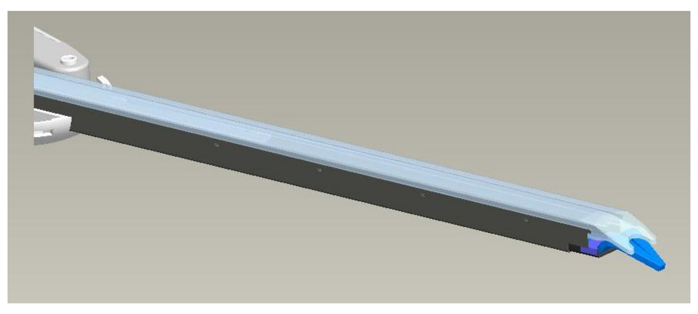

Fig. 2 Front end of biomedical instrument

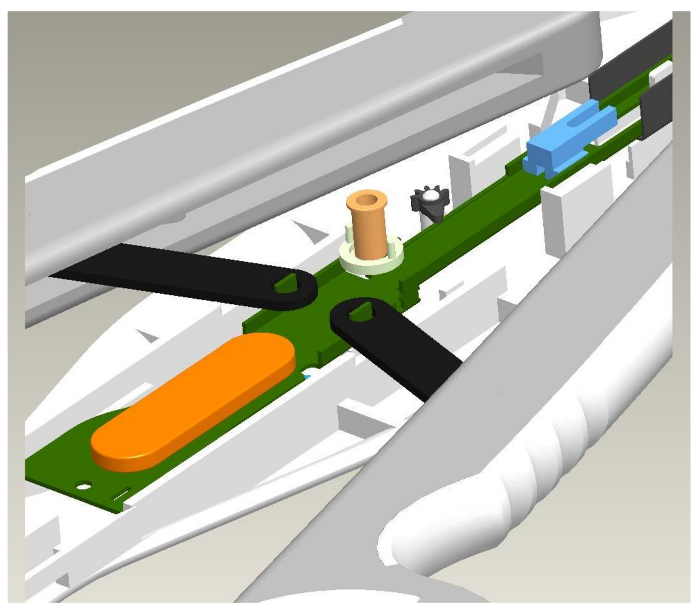

Fig. 3 Inside mechanism of biomedical instrument

Computer Modeling and Analysis

The energy balance equation of this instrument driving mechanism can be shown as follows:

$$F_{load} * V_{linear} = T * \omega \qquad (1)$$

Since the torque is

$$T = F_{pivot} * R,$$

So,

$$T * \omega = F_{pivot} * R * \omega$$
$$= F_{pivot} * V_{angular} \qquad (2)$$

In the above equation,

T - torque on trigger pivot point
ω – angular speed of handle at pivot
F_{load} – load on drive bar
V_{linear} – linear velocity of drive bar
$V_{angular}$ – angular velocity at handle pivot point
R – distance between handle pivot point and surgeon's finger position

So,

$$F_{load} * V_{linear} = F_{pivot} * V_{angular} \qquad (3)$$
$$F_{load} = (V_{angular} / V_{linear}) * F_{pivot}$$
$$= (VR) * F_{pivot} \qquad (4)$$

(VR) – velocity ratio

From the geometry of this instrument trigger handle setup:

$$F_{finger} * 4.755 = F_{pivot} * 2.300 \qquad (5)$$

$$F_{pivot} = 2.067 * F_{finger}$$

Then,

$$F_{load} = (VR) * F_{pivot}$$
$$= (VR) * 2.067 * F_{finger} \qquad (6)$$

The simulated result of computer modeling on instrument driving mechanism is predicted in Fig. 4 and the mechanical advantage at full trigger and handle close of the surgical clip is:

Mechanical advantage = (VR) * 2.067
= (.04877 / .03545) * 2.067
= 2.844 (7)

The above result represents that if 20 lb force is needed to fully form or close the surgical clip, the force loaded on surgeon's finger will be 3.516 lbs which are lower than the normal spec of 4 lbs in surgical operation procedure and meet the surgeons' satisfaction and requirement.

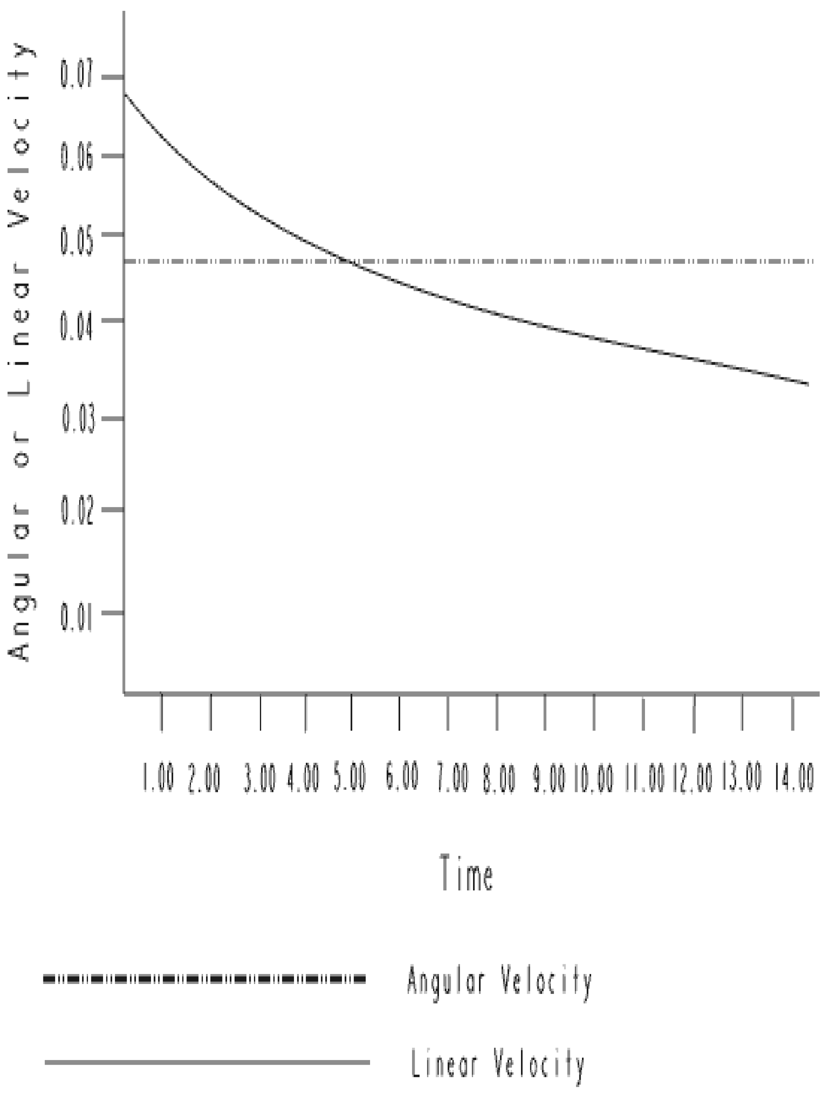

Fig. 4 Simulation results on driving mechanism

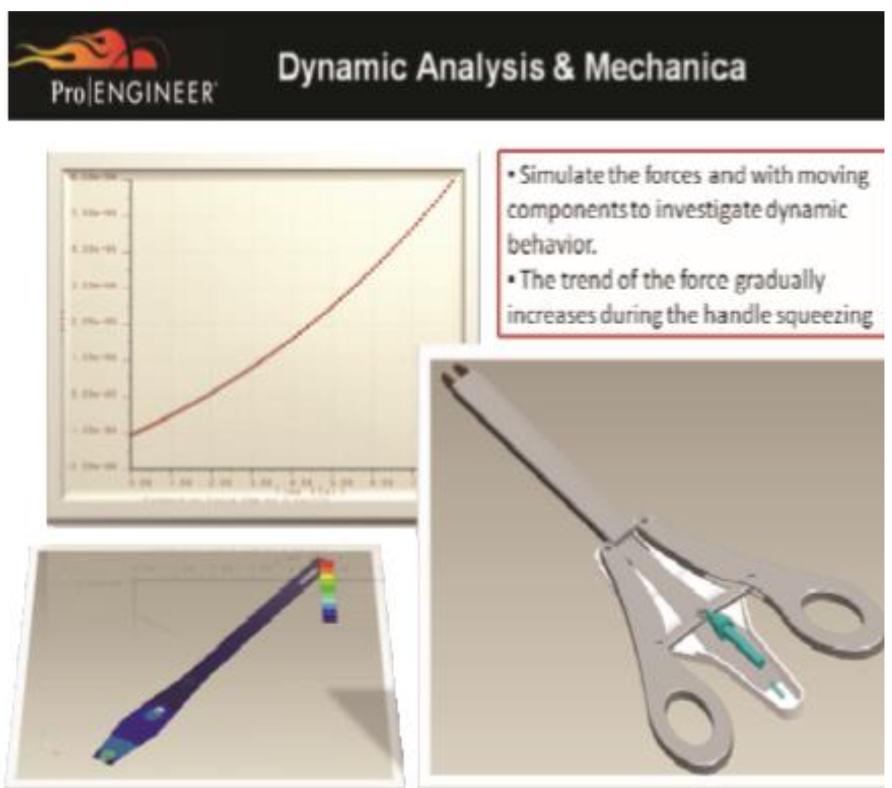

Fig. 5 FEM analysis on driving system

CONCLUSION

The controlled and feasible functionality of this new biomedical/surgical instrument has been verified from the apparatus model and functional study, computerized modeling/analysis and prototype lab testing. The primary improved features of this instrument, compared with the current existing apparatus, include: the surgical clip advancement is proper guided and well controlled, the instrument mechanical driving system is less complex and more compact, jaw setup is strengthened to prevent its twist, and the apparatus is kept from being manipulated while not in operation by proposing a well guided wedge plate. The prototype of this biomedical surgical instrument is being sent to the hospitals and medical industry for surgeons further evaluations.